

**Exhibit 1**

**Defendants' September 13, 2024 Letter to Government**



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**By Electronic Mail**

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**Re: *United States of America v. AmerisourceBergen Corp. et al.* (No. 22-cv-5209-GJP)**

Amy and Mike,

Following Judge Pappert's decision (ECF No. 82) and our meet and confer on September 10<sup>th</sup>, we write seeking clarity on the Government's position on production of internal DEA documents. As agreed on our meet and confer, we look forward to receiving the Government's response to this letter by next Friday (September 20<sup>th</sup>).

The Government informed Defendants and the Court that it agreed to search for and produce internal DEA documents (1) "that relate to external communications (e.g., DEA documents that reflect or discuss communications between DEA and Defendants or other third parties, such as industry groups)"; (2) "concerning Defendants and the facts in this case (e.g., internal DEA documents discussing Defendants' suspicious-order-monitoring systems)"; and (3) "regarding the interpretation of the SORs laws from specific DEA personnel whom Defendants contend provided them with advice about the SORs laws inconsistent with the Government's legal theory." ECF No. 81 (7/12/2024 Letter to the Court). As we have previously explained, the Government's proposal does not make clear what documents the Government intends to withhold.

Further compounding the confusion, the Government informed Defendants on the meet and confer that it *would not*, in fact, produce all internal DEA documents that fall within these categories. That is because, as the Government first made clear during our meet and confer, the Government's interpretation of these three categories is extremely and artificially narrow.

For example, the Government has now stated it will neither produce nor even log (to the extent privileged) internal communication about the *Masters* decision (and other legal decisions the Government has put at issue) even though the Government itself relies on that case in its Interrogatory responses and any such

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communication (whether internal or external) clearly relates to the “facts in this case.” Notably, in response to specific questions from industry about how to interpret and apply *Masters*, the DEA refused to provide guidance and instead referred industry to the then-forthcoming Notice of Proposed Rulemaking. Yet, the Government is now refusing to produce documents involving internal discussions relating to the revised regulation that DEA proposed in 2020. Those documents clearly involve communications with industry (including Defendants) and relate to the facts of this case and, accordingly, fall within the first and third categories of documents the Government previously agreed to produce. Surprisingly, the Government stated it would withhold such communications as “irrelevant.” It thus has become clear that the Government does indeed intend to treat its proposed agreement to produce internal DEA documents as a black box, where the search for, collection, production, and logging of any document is subject to the Government’s unilateral, subjective, and self-serving assessment of “relevance.”

For example, will the Government produce internal DEA communications that do not specifically reference Defendants that are otherwise responsive to these Requests? Will the Government produce internal DEA communications discussing the subject of communications that eventually went to third-parties (e.g., the proposed 2020 amended regulation, *Masters*)? Will the Government produce internal DEA communications regarding the interpretation of the SOR laws from someone who did not communicate directly with Defendants (e.g., communicated with another third-party or communicated with someone who ultimately did communicate with Defendants)? Does the Government’s calculus change on what it is withholding based on the person’s position at DEA, and if so, where is the Government drawing the line? These are only examples, as Defendants do not know what types of information is contained in DEA’s documents and can, therefore, only guess at what kind of documents the Government may be unilaterally withholding.

Moreover, the Government stated that it would not treat internal DEA communications differently depending on whether that communication came from a lower-level employee or a higher-level employee. This is particularly troubling because we know from the DEA’s limited, third-party MDL productions of internal communications that DEA officials, including high ranking officials, were aware of industry concerns over the lack of consistent guidance from DEA regarding suspicious order reporting requirements for many years.

Based on our meet and confer, Defendants remain concerned that the Government is withholding responsive, relevant documents and improperly limiting the meaning of the categories of internal DEA documents it *already* agreed to produce. To that end, please define the following terms from the categories of documents the Government informed the Defendants and the Court it would be willing to produce: “relate”; “concerning”; “facts in this case”; and “regarding.”

Additionally, below is a list of specific Requests for Production. For each Request, please provide the Government’s position as to what specific categories of internal DEA documents the Government does not intend to produce or log and on what basis the Government is withholding those documents. To be clear, Defendants are looking for detailed and specific information about what the Government intends to produce and what the Government intends to withhold to better understand the three categories of internal DEA documents the Government has previously agreed to produce. We expect the Government to state its position as to each Request listed below.

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If the Parties are at an impasse, Defendants intend to move to compel the Government to produce documents responsive to these Requests—namely internal DEA communications that the Government intends to withhold that are otherwise responsive to these Requests.

**Requests for Production Defendants Seek Clarity On:**

*Defendants' First Set of Requests for Production (as-modified by Defendants' April 10, 2024 letter to the Government)*

- RFP 2 - From 2014 through the filing of the complaint, all DEA Documents regarding the meaning of Suspicious Order, including but not limited to any ambiguity, vagueness, imprecision, or subjectivity in the meaning or application of the term.
- RFP 3 - From 2007 through the filing of the complaint, all DEA Documents regarding whether or how the Suspicious Order Monitoring and Reporting Obligations apply to “orders of interest” (or other similar terminology used to describe orders that hit a Registrant’s threshold, parameter, or algorithm).
- RFP 7 - All DEA Documents from 2015 through the filing of the complaint regarding: a. the DEA’s interpretation or understanding of the Masters Decisions; b. any Rule You contend was created or otherwise established by either of the Masters Decisions; c. the DEA’s internal or external guidance or training materials regarding the Masters Decisions; and d. requests to DEA for guidance about the Masters Decisions (including the NACDS Letter), and the DEA’s response (or lack thereof) to such requests.
- RFP 9 - From 2007 through the filing of the complaint, all Communications between the DEA and any industry group or trade association, including but not limited to the Healthcare Distribution Management Association, Healthcare Distribution Alliance, and National Association of Chain Drug Stores, regarding the Suspicious Order Monitoring and Reporting Obligations, what constitutes a Suspicious Order, how to design and operate a suspicious order monitoring system, and/or any other diversion control obligations for distributors of controlled substances, and all Documents regarding such Communications including but not limited to notes or summaries of meetings or phone calls.
- RFP 12 - All DEA, DOJ, OIG, GAO, and OMB Documents from 2014 through the filing of the complaint regarding the 2020 SOR Notice, including but not limited to: a. All drafts of the 2020 SOR Notice; b. All calculations of estimated times, costs, and reports of Suspicious Orders as set forth in the 2020 SOR Notice; c. the drafting, formulation, internal approvals, and issuance of the 2020 SOR Notice; d. all comments received in response to the 2020 SOR Notice and all Documents regarding such comments; e. all Communications regarding the 2020 SOR Notice with any other branch, agency, or instrumentality of the United States, including but not limited to Congress, DOJ, GAO, OIG, and OMB, and all Documents regarding such Communications; f. the timing of the issuance of the 2020 SOR Notice, including the reasons for any delays; and g. the status of the proposed rule announced by the 2020 SOR Notice.

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- RFP 67 - All DEA Documents from 2007 through the filing of the complaint relating to DEA statements to Registrants not to report every order that is flagged by a Registrant's suspicious order monitoring system, including but not limited to at the May 10-11, 2016 HDMA conference.

*Defendants' Second Set of Requests for Production*

- RFP 3 - All Documents and Communications at DEA, including internal DEA communications, related to the National Association of Chain Drug Stores' letter to DEA dated February 6, 2018 requesting clarification on the 2017 D.C. Circuit Court opinion issued in *Masters Pharmaceutical, inc. v. Drug Enforcement Administration*.
- RFP 7 - All Documents and Communications at DEA, including internal DEA communications, related to a July 8, 2010 letter from HDMA to DEA.
- RFP 8 - All Documents and Communications at DEA, including internal DEA communications, related to the December 7, 2010 meeting between DEA and the Healthcare Distribution Management Association ("HDMA"), the scheduled July 31, 2013 meeting between DEA and HDMA that was cancelled by DEA, and questions the HDMA submitted to DEA on June 1, 2011 and July 2, 2013.
- RFP 9 - All Documents and Communications at DEA, including internal DEA communications, related to a December 19, 2011 presentation by HDMA to DEA.
- RFP 11 - All Documents and Communications at DEA, including internal DEA communications, related to the Distributor Initiative Meeting held at National Harbor on October 22, 2013.
- RFP 17 - All Documents and Communications at DEA, including internal DEA communications, related to a conversation between HDMA and Lou Milione of DEA on or about November 13, 2015.
- RFP 18 - All Documents and Communications at DEA, including internal DEA communications, related to a meeting between HDMA and DEA on February 29, 2016.
- RFP 19 - All Documents and Communications at DEA, including internal DEA communications, related to the DEA Distributor Conference on May 10-11, 2016.
- RFP 20 - All Documents and Communications at DEA, including internal DEA communications, related to the Distributor Initiative Briefing in North Carolina on August 21, 2017.
- RFP 21 - All Documents and Communications at DEA, including internal DEA communications, related to an HDA conference attended by DEA on or about March 11, 2019.
- RFP 23 - All Communications between DEA and Registrants regarding *In re Masters Pharm., Inc.*, 80 Fed. Reg. 55418, 55477-78 (Drug Enf't Admin. 2015), *pet. for review denied sub nom. Masters Pharm., Inc. v. DEA*, 861 F.3d 206 (D.C. Cir. 2017), including all internal DEA communications regarding *Masters'* impact on Registrants' obligations under 21 C.F.R. § 1301.74.

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- RFP 25 - All Communications related to *In re Nat'l Prescription Opiate Litig.*, MDL No. 2804, 2019 U.S. Dist. LEXIS 140020, at \*61-64, 71-72 (N.D. Ohio Aug. 19, 2019), including internal DEA Communications, Communications with Registrants, and Communications with third parties, including but not limited to Communications with counsel for Plaintiffs.
- RFP 26 - All Communications related to *City & Cnty. of S.F. v. Purdue Pharma L.P.*, 491 F. Supp. 3d 610, 631-32 (N.D. Cal. 2020), including internal DEA Communications, Communications between DEA and Registrants, and Communications between DEA and third parties, including but not limited to Communications with counsel for Plaintiffs.
- RFP 27 - All Communications related to *Cherokee Nation v. McKesson Corp.*, 529 F. Supp. 3d 1225, 1235 (E.D. Okla. 2021), including internal DEA Communications, Communications between DEA and Registrants, and Communications between DEA and third parties, including but not limited to Communications with counsel for Plaintiffs.

Very truly yours,

/s/ Joseph J. Mahady  
Joseph J. Mahady